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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,526	02/10/2000	Kuanghui Lu	CIBT-P01-058	1398

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FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

DEBERRY, REGINA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/499,526	Applicant(s) LU ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 15-20, 30-33, 39, 45, 46, 53, 54, 78, 87, 90-94, 96-98, 100, 101 and 130 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/05, 1/06</u> . | 6) <input type="checkbox"/> Other: _____  |

***Status of Application, Amendments and/or Claims***

The amendment filed 19 January 2006 has been entered in full. Claim 124 is cancelled. Claims 13, 15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-94, 96-98, 100-112, 116-123, 125-130 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The rejection to claims 13, 15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-94, 96-98, 100-112, 116-130 under 35 USC 112, first paragraph, scope of enablement, as set forth at pages 5-6 of the previous Office Action (17 October 2005) is *withdrawn* in view of the amendment (19 January 2005).

The rejection to claims 23, 89, 102-105, 108, 111 and 118 under 35 USC 103(a) as being unpatentable over Morley *et al.*, Life Sciences, Vol. 41, pgs 2157-2165 (1987), as set forth at pages 7-8 of the previous Office Action (17 October 2005) is *withdrawn* in view of the amendment (19 January 2005). Please note that the 35 U.S.C. 103(a) rejection as being unpatentable over Morley *et al.* was withdrawn because of the limitations in the newly amended claims. The rejection will be reapplied to the instant claims if the claim language is amended. Please see the 35 U.S.C. 112, first paragraph, written description, new matter rejection and the maintained 35 U.S.C. 112, first paragraph, enablement rejection below. However, amending the instant claims to recite,

"...wherein said PYY agonist or biologically active fragment thereof binds a PYY receptor and promotes glucose responsiveness of pancreatic cells", would obviate the instant rejection.

The rejection to claims 13, 21, 87, 88, 93, 94 and 102 under 35 USC 112, second paragraph, as set forth at pages 8-9 of the previous Office Action (17 October 2005) is *withdrawn* in view of the amendment (19 January 2005).

**Claim Rejections - 35 USC § 112, First Paragraph, Enablement**

Claims 21, 23, 28, 29, 50, 57-60, 76, 77, 85, 88, 89, 102-112, 116-123, 125-129 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The basis for this rejection (for claims 109, 112, 119) is set forth at pages 3-4 of the previous Office Action (17 October 2005).

Applicant states that they have presented working examples demonstrating the ability of PYY to affect glucose responsiveness and have pointed to several places in the specification and claims as filed which provide enabling support for the use of a PYY agonist or biologically active fragment thereof effective to treat a disease associated with glucose metabolism. Applicant states that it is well known to the skilled artisan that several diseases associated with altered glucose metabolism are accompanied by adverse effects or symptoms such as hyperlipidemia and/or hyperlipoproteinemia. Applicant argues that it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement made in a supporting disclosure and to back up assertions of its own with acceptable evidence

or reasoning which is inconsistent with the contested statement. Applicant cites case law.

Applicant's arguments have been fully considered but are not deemed persuasive. The Examiner fully stated in the previous Office Action, why it doubts the enablement of the instant disclosure. Hyperlipidemia or hyperlipoproteinemia is defined as elevated concentrations of any or all lipids in the plasma, such as cholesterol, triglycerides and lipoproteins. As was stated in the last Office Action, the Examiner does not deny an association between glucose metabolism and lipid metabolism. However, the instant specification fails to demonstrate that **PYY alleviates hyperlipidemia or hyperlipoproteinemia** (Emphasis added). The specification fails to teach a reduction in plasma free fatty acid (FFA) concentrations upon PYY administration (demonstrating PYY stimulates lipolysis). The instant claims, as recited, read on PYY affecting hyperlipidemia or hyperlipoproteinemia.

In addition, the newly amended claims now recite, "alleviates at least one adverse effect or symptom of said disease associated with altered glucose metabolism". Alleviating at least one adverse effect or symptom of said disease associated with abnormal glucose metabolism could encompass many diverse effects/symptoms associated with abnormal glucose metabolism. The specification demonstrates that PYY promotes glucose responsiveness of pancreatic cells. However, this activity is not tantamount to "alleviating hyperlipidemia or hyperlipoproteinemia" or the broad claim of "alleviating at least one adverse effect or symptom of said disease associated with abnormal glucose metabolism".

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

**NEW REJECTIONS:**

**Claim Rejections -35 USC § 112, First Paragraph, Written Description (New Matter)**

Claims 109, 112, 119 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "at least one adverse effect or symptom of said disease associated with altered glucose metabolism comprises hyperlipidemia or hyperlipoproteinemia".

The wording or connotation of the instant claims in Applicant's amendment (filed 19 January 2006) is not readily apparent. The Examiner has located a limitation in the instant specification, which states "at least one adverse effect or symptom, e.g., absolute or relative insulin deficiency, fasting hyperglycemia, glycosuria, development of atherosclerosis, microangiopathy, nephropathy, and neuropathy of diseases characterized by insufficient insulin activity" (page 26, lines 19-22). The Examiner cannot locate the limitation, "at least one adverse effect or symptom of said disease associated with altered glucose metabolism comprises hyperlipidemia or hyperlipoproteinemia".

The specification does not provide direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

### ***Conclusion***

Claims 13, 15-20, 30-33, 39, 45, 46, 53, 54, 78, 87, 90-94, 96-98, 100, 101 and 130 are allowed.

Claims 21, 23, 28, 29, 50, 57-60, 76, 77, 85, 88, 89, 102-112, 116-123, 125-129 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.




Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RMD  
3/22/06

  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
3/29/06  
AU1647

Continuation of Disposition of Claims: Claims pending in the application are 13,15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-94, 96-98,100-112,116-123 and 125-130.

Continuation of Disposition of Claims: Claims rejected are 21, 23, 28, 29, 50, 57-60, 76, 77, 85, 88, 89, 102-112,116-123 and 125-129.